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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,622	12/31/2003	Sue K. DeNise	MMI1150	2415
28213	7590	10/03/2006	EXAMINER	
DLA PIPER US LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			THOMAS, DAVID C	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,622	DENISE ET AL.	
	Examiner	Art Unit	
	David C. Thomas	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-27, 43-47, and 49-51, drawn to methods to infer breed of a bovine subject from a nucleic acid sample of the subject, classified in class 435, subclasses 6 and 91.2.
 - II. Claims 28-40 and 52-55, drawn to isolated polynucleotides and vectors or cells comprising the polynucleotides, oligonucleotides and primers that bind to the polynucleotides, and kits comprising the oligonucleotides and primers, classified in class 536, subclasses 23.1, 24.31, and 24.33 and class 435, subclasses 320.1 and 252.3.
 - III. Claim 48, drawn to a bovine subject, classified in class 800, subclass 15.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions in Groups II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group II, drawn to isolated polynucleotides and vectors or cells comprising the polynucleotides, oligonucleotides and primers that bind to the polynucleotides, and kits comprising the oligonucleotides and primers, can be used in other process in addition to SNP

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detection, such as DNA sequencing, primer extension and nucleic acid amplification assays, and *in situ* assays.

Furthermore, searching the inventions of Group I and Group II would impose a serious search burden. The inventions of Group I and Group II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods to infer breed of a bovine subject from a nucleic acid sample of the subject and isolated polynucleotides and vectors or cells comprising the polynucleotides, oligonucleotides and primers that bind to the polynucleotides, and kits comprising the oligonucleotides and primers is not coextensive. Group II encompasses primers and/or probes used in identifying SNPs, which are not required for the Search of Group I. The search for Group I would require a text search for the methods of identifying SNPs associated with a bovine breed, which is not required for the search of Group II.

4. Inventions in Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the methods to infer breed of a bovine subject from a nucleic acid sample of the subject in Group I, including methods for breeding a bovine subject based on methods of inferring breed of a bovine candidate in breeding programs, can be used to make other bovine subjects with different SNPs and

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therefore different traits, while the bovine subjects in Group II can be made by other breeding methods or based on different inferred traits.

Furthermore, searching the inventions of Group I and Group III would impose a serious search burden. The inventions of Group I and Group III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for methods to infer breed of a bovine subject from a nucleic acid sample of the subject and a bovine subject is not coextensive. Group III encompasses domestic farm animals resulting from selection and breeding, which are not required for the Search of Group I. The search for Group I would require a text search for the methods of identifying SNPs associated with a bovine breed, which is not required for the search of Group III.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups II and III are not used in the same processes. The invention of Group II, drawn to isolated polynucleotides and vectors or cells comprising the polynucleotides, oligonucleotides and primers that bind to the polynucleotides, and kits comprising the oligonucleotides and primers, can be used in processes such as SNP detection, DNA sequencing, primer extension and nucleic acid amplification assays, and *in situ* assays, while the invention of Group III, drawn to a bovine subject, represents the product of a breeding program that can be used for further breeding, or other uses such

as food production. The polynucleotides and oligonucleotides of Group II are isolated nucleic acids or vectors, while the products of Group III are whole animals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. In particular, there is a significant search burden because entirely different searches of Group II and Group III will be required for the primers and/or probes used in identifying SNPs of Group II and the domestic farm animals resulting from selection and breeding of Group III.

Sequence election

6. This application contains claims directed to 9,743 patently distinct inventions, specifically, the individual SEQ ID Nos. 1-4868, 4879-9736, 64887-64895, and 64914-64922. Furthermore, the sequence searching in multiple expansive databases has put undue burden on the examiner and office resources. Applicant is required to elect a single polynucleotide sequence from the group of the SEQ ID NOS 1-4868 and 64887-64895 representing one SNP, and to elect a single oligonucleotide sequence from the group of the SEQ ID NOS 4879-9736 and 64914-64922. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David C. Thomas
9/28/06

[Signature]
JEFFREY FREDMAN
PRIMARY EXAMINER
9/28/06